K112075

SEP 15 2011

BIOMÉRIEUX

# 510(k) SUMMARY

## VITEK® 2 AST-ST Ampicillin

**510(k) Submission Information:**

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|---|---|
| Submitter's Name: | bioMérieux, Inc. |
| Address: | 595 Anglum Road<br>Hazelwood, MO 63042 |
| Contact Person: | Jolyn Tenllado<br>Director, Regulatory Affairs |
| Phone Number: | 314 -731-8386 |
| Fax Number: | 314-731-8689 |
| Date of Preparation: | September 2011 |

**B. Device Name:**

| | |
|---|---|
| Formal/Trade Name: | VITEK® 2 *Streptococcus* Ampicillin |
| Classification Name: | Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device, 21 CFR 866.1645<br>Product Code LON |
| Common Name: | VITEK® 2 AST-ST Ampicillin |

**C. Predicate Device:** VITEK® 2 Gram Positive Amoxicillin for Streptococcus pneumoniae (K063597)

**D. 510(k) Summary:**

VITEK® 2 AST-ST Ampicillin is designed for antimicrobial susceptibility testing of Streptococcus species.
VITEK® 2 AST-ST Ampicillin is a quantitative test intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents.
Ampicillin has been shown to be active against the microorganisms listed below:
Beta-hemolytic group *Streptococcus* species
Viridans group *Streptococcus* species

The antimicrobial agent presented in VITEK® 2 AST Cards is in concentrations equivalent by efficacy to standard method concentrations in mcg/ml. The VITEK® 2 AST Cards are essentially miniaturized versions of the doubling dilution technique for determining the minimum inhibitory concentration (MIC) microdilution methodology.

The bacterial isolate to be tested is diluted to a standardized concentration in 0.45 - 0.50% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK® 2 System automatically fills, seals and places the card into the incubator/reader. The VITEK® 2 Compact has a manual filling and sealing operation. The VITEK® 2 monitors the growth of each well in the card over a defined period of time (up to 36 hours for yeast). At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antimicrobial contained on the card.

VITEK® 2 AST-ST Ampicillin demonstrated substantially equivalent performance when compared with the CLSI broth microdilution reference method, as defined in the FDA Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA. Issued August. 28, 2009.

The Premarket Notification (510[k]) presents data in support of VITEK® 2 AST-ST Ampicillin. An external evaluation was conducted with fresh and stock clinical isolates, as well as a set of challenge strains. The external evaluations were designed to confirm the acceptability of VITEK® 2 AST-ST Ampicillin by comparing its performance with the CLSI broth microdilution reference method. The data is representative of performance on both the VITEK® 2 and VITEK® 2 Compact instrument platforms. VITEK® 2 AST-ST Ampicillin demonstrated acceptable performance of 99.1% overall essential agreement and 97.0% overall category agreement with the reference method. Reproducibility and Quality Control demonstrated acceptable results using both the VITEK® 2 and VITEK® 2 Compact instrument systems.

**bioMérieux, Inc.**
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

bioMérieux, Inc.
c/o Jolyn Tenllado
Director, Regulatory Affairs
595 Anglum Rd.
Hazelwood, Missouri 63042

SEP 15 2011

Re: K112075
Trade/Device Name: VITEK® 2 Streptococcus Ampicillin
Regulation Number: 21 CFR§ 866.1645
Regulation Name: Short-Term Antimicrobial Susceptibility Test System
Regulatory Class: Class II
Product Code: LON
Dated: July 19, 2011
Received: July 20, 2011

Dear Ms. Tenllado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K112075

Device Name: VITEK® 2 *Streptococcus* Ampicillin
( ≤ 0.25 – ≥ 16 µg/mL)

Indications For Use:

VITEK® 2 *Streptococcus* Ampicillin is designed for antimicrobial susceptibility testing of Streptococcus species. VITEK® 2 *Streptococcus* Ampicillin is a quantitative test intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. Ampicillin has been shown to be active against the microorganisms listed below:
Beta-hemolytic group *Streptococcus* species
Viridans group *Streptococcus* species

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 System for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus spp.* and clinically significant yeast.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Freddie M. Poole

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K112075